

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

JENNIFER ZERBATO, Individually  
and on behalf of all others similarly situated,

Plaintiff,

v.

ALLOVIR, INC., DIANA M. BRAINARD,  
and VIKAS SINHA,

Defendants.

Civil Action No. 1:24-cv-10152-DJC

**AMENDED CLASS ACTION COMPLAINT**

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1. Lead Plaintiffs Harry Levin and Julio Maurice Bueno (“Plaintiffs”) through Lead Counsel, bring this securities class action on behalf of themselves and all other persons or entities who purchased AlloVir, Inc. securities between January 11, 2023 and December 21, 2023, inclusive (the “Class Period”), and were damaged thereby, against Defendants AlloVir, Inc. (“AlloVir” or the “Company”), Diana M. Brainard, and Vikas Sinha (collectively, the “Individual Defendants” and with AlloVir, “Defendants”) for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), and Rule 10b-5 promulgated thereunder.

2. Plaintiffs make the following allegations upon information and belief, except as to those allegations concerning Plaintiffs, which Plaintiffs allege upon personal knowledge. Plaintiffs’ information and belief are based upon Lead Counsel’s investigation, which included a review and analysis of, *inter alia*: (i) regulatory filings made by AlloVir with the United States Securities and Exchange Commission (“SEC”); (ii) a review and analysis of AlloVir’s conference calls including conference calls on which Defendants participated; (iii) AlloVir press releases; (iv) AlloVir’s filings with the National Library of Medicine Clinical Trials Database; (v) analyst reports and advisories about the Company; and (vi) information readily obtainable on the internet concerning U.S. Food and Drug Administration (“FDA”) and National Institutes of Health (“NIH”) clinical trials. Plaintiffs believe that additional substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## **I. SUMMARY OF THE ALLEGATIONS**

3. AlloVir is a late clinical-stage cell therapy company that researches allogeneic T cell therapies for the treatment and prevention of various viral diseases. Since the Company’s inception in 2013, it has never developed or commercialized an FDA approved product, nor has the Company ever generated revenue.

4. AlloVir's lead product prospect is posoleucel, which is intended to provide a "multi-VST therapy that targets six viruses."

5. Prior to the Class Period, posoleucel showed promise that it would be commercially viable because of excellent Phase 2 FDA study results finding it was safe and effective. These results led the Company to begin the Phase 3 FDA trials, which is effectively the last step before gaining FDA approval to sell posoleucel commercially.

6. During the Class Period, posoleucel was in three different Phase 3 trials for different applications. One of the Phase 3 trials related to posoleucel's efficacy for the prevention of the six target viruses (the "MVP Phase 3 Trial"). The other two Phase 3 trials related the posoleucel's efficacy for the treatment of certain of the six target viruses and complications related to those viruses (the "ADV Phase 3 Trial" and "VHC Phase 3 Trial") (collectively, the "Trials").

7. Unbeknownst to investors, Defendants designed each of the Trials with a mechanism that enabled Defendants to review interim results of the Trials while the Trials were ongoing, in order for the Company to terminate any of the Trials if it was futile to proceed. AlloVir wrote this protocol into the Trials, and it only became public well after the Class Period.

8. Through the futility analysis, by at least the first day of the Class Period, Defendants knew the MVP Phase 3 Trial was futile. Later, during the Class Period, Defendants learned that the ADV Phase 3 Trial and VHC Phase 3 Trial were also futile.

9. Defendants misled investors by repeatedly touting positive posoleucel's Phase 2 results and stating that the Phase 3 Trials were ongoing, all while knowing that the Phase 2 results were rendered meaningless by the Company's trilogy of failures in the Phase 3 Trials. As a result, there was no viable path to commercialize posoleucel based on the results from the Trials.

10. While AlloVir's common stock price was artificially inflated by concealing the Trials' futility results, the Company offered 20 million shares of its common stock for sale and raised millions of dollars from the Class.

11. On December 22, 2023, Defendants shocked the market by finally revealing that all three Phase 3 Trials were terminated because it would be futile for each of the Trials to proceed through the FDA approval process when the preliminary Phase 3 results decisively showed that posoleucel was ineffective for its stated purpose.

12. Analysts expressed their shock by the news of the abrupt and supposedly simultaneous failure of the Trials, with one stating "*we are doubly surprised in that it was never disclosed that these trials had planned futility analyses baked into their design, let alone the timing.*"<sup>1</sup>

13. The market reacted negatively and the price of AlloVir common stock plummeted by over 67%, causing millions of dollars in losses to Class members.

## **II. JURISDICTION AND VENUE**

14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC. *See* 17 C.F.R. § 240.10b-5.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1331 and section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this judicial district.

16. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the

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<sup>1</sup> All emphasis is added unless otherwise noted.

United States mail, interstate telephone communications, and the facilities of national securities exchanges.

### **III. PARTIES**

17. Lead Plaintiff Harry Levin, as set forth in the certification submitted with his motion for appointment as lead plaintiff, incorporated by reference herein, purchased AlloVir securities during the Class Period and suffered damages as a result of the federal securities law violations alleged herein.

18. Lead Plaintiff Julio Maurice Bueno, as set forth in the certification submitted with his motion for appointment as lead plaintiff, incorporated by reference herein, purchased AlloVir securities during the Class Period and suffered damages as a result of the federal securities law violations alleged herein.

19. Defendant AlloVir is a Delaware corporation with principal executive offices located at 1100 Winter Street, Waltham, Massachusetts 02451. AlloVir’s securities trades in an efficient market on the Nasdaq Global Select Market (“NASDAQ”) under the ticker symbol “ALVR.”

20. Defendant Diana M. Brainard (“Brainard”) has served as the Company’s Chief Executive Officer at all relevant times. Defendant Brainard has served as a member of the Board of Directors of AlloVir since July 2020 and as its Chief Executive Officer since May 2021. Defendant Brainard has more than 20 years of experience in the biopharmaceutical industry. Prior to joining AlloVir as its Chief Executive Officer Defendant Brainard served as Senior Vice President and Virology Therapeutic Area Head at Gilead Sciences, Inc. from 2018 to 2021.

21. Defendant Vikas Sinha (“Sinha”) has served as the Company’s Chief Financial Officer and President at all relevant times. Defendant Sinha has served as AlloVir’s Chief Financial Officer and President since January 2019. Defendant Sinha has over 20 years of

experience working in executive finance roles in the life sciences industry. Prior to joining AlloVir as its Chief Financial Officer and President, Defendant Sinha served as the Chief Financial Officer of Alexion Pharmaceuticals for more than 11 years.

22. Defendants Brainard and Sinha possessed the power and authority to control the contents of AlloVir’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of AlloVir’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with AlloVir, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially misleading. The Individual Defendants are liable for the misleading statements and omissions pleaded herein.

#### **IV. SUBSTANTIVE ALLEGATIONS**

##### **A. Background**

23. AlloVir was founded in 2013 and became a public company in August 2020.

24. AlloVir has never earned revenue. *See* February 15, 2023 SEC Form 10-K at 86.

25. The Company’s operations are largely financed through the sale of equity to investors. *See* February 15, 2023 SEC Form 10-K at 110.

26. AlloVir describes itself as “a leading late clinical-stage cell therapy company developing highly innovative allogeneic T cell therapies to treat and prevent devastating viral diseases. The Company’s innovative and proprietary virus-specific T cell, or VST, therapy platform allows AlloVir to generate off-the-shelf VSTs designed to restore immunity in patients

with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases.”  
 AlloVir 3Q2023 SEC Form 10-Q.

27. AlloVir represented that “[t]here is an urgent medical need for therapies to treat a large number of patients suffering from viral diseases who currently have limited or no treatment options.”

28. AlloVir’s lead product, posoleucel, purports to be a “multi-VST therapy that targets six viruses: adenovirus, or AdV, BK virus, or BKV, cytomegalovirus, or CMV, Epstein-Barr virus, or EBV, human herpesvirus 6, or HHV-6 and JC virus, or JCV. The Company believes that posoleucel has the potential to fundamentally transform the treatment landscape for transplant patients by substantially reducing or preventing disease morbidity and mortality, thereby dramatically improving patient outcomes.”

29. Posoleucel has not been approved by the FDA and was being studied in clinical trials for distinct indications – [1: the MVP Phase 3 Trial] the prevention of clinically significant infections from multiple viruses, [2: the VHC Phase 3 Trial] the treatment of virus-associated hemorrhagic cystitis, or HC, and [3: the ADV Phase 3 Trial] the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or allo-HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel.

30. The FDA requires that a company seeking to sell a pharmaceutical product (in industry parlance, a “sponsor”) first obtain the FDA’s approval.

31. The FDA’s grant of approval requires the sponsor to show substantial scientific evidence demonstrating that the product is safe and effective for its intended use. The sponsor shows such substantial scientific evidence through “adequate and well-controlled investigations,

including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved.” 21 U.S.C. § 355(d).

32. A sponsor conducts clinical trials in three phases. These phases are codified in FDA regulations as follows:

**Phase I.** Phase I studies “are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”

**Phase II.** Phase II studies are “typically well controlled” studies “conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug.”

**Phase III.** Phase III studies are expanded studies “performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.”

21 C.F.R. § 312.21.

33. The sponsor, not the FDA, is responsible for designing clinical trials and the protocols for clinical trials.

34. The FDA requires sponsors to register clinical trials conducted even in part within the United States with the NIH run clinical trial registry data bank, ClinicalTrials.gov (the “Clinical Trials Website”). *See* 21 U.S.C. § 331(jj)(2).

35. To reduce the risk of bias, sponsors frequently design clinical trials as placebo-controlled, randomized, and double-blind. Meaning, participants are randomly assigned to receive either the drug being studied or a placebo, and no one involved with the trial, including the participant, their doctor, and the sponsor, knows what treatment is to be given to each trial participant at the time.

36. A sponsor can design its clinical trials with a Data Safety Monitoring Board (“DSMB”). A DSMB is an independent group of experts that monitors patient safety and treatment efficacy data while a clinical trial is ongoing. While the primary responsibility of a DSMB is to protect patient safety, sponsors also frequently design clinical trials with a DSMB mandate to perform a futility analysis at an early stage in the trial, and make a recommendation to the sponsor on the continuation of the study. *See generally* (<https://www.fda.gov/media/176107/download>) and (<https://www.niams.nih.gov/grants-funding/data-safety-monitoring/dsm-guidelines>).

37. A DSMB’s futility analysis reviews efficacy data from an initial subset of participants to determine if, based on the initial results, there is no longer a reasonable likelihood that the trial will reach a conclusion of effectiveness. When this occurs, the DSMB typically reports the results of its futility analysis to the sponsor so that the trial can be stopped to conserve resources for the sponsor. *See generally* (<https://www.fda.gov/media/176107/download>) and (<https://www.niams.nih.gov/grants-funding/data-safety-monitoring/dsm-guidelines>).

#### **B. AlloVir Receives Multiple Positive Posoleucel Phase 2 Results**

38. In June 2014, AlloVir initiated the Phase 2 Proof of Concept Study of posoleucel, referred to as the CHARMS study (the “CHARMS Phase 2 Study”). *See* <https://clinicaltrials.gov/study/NCT02108522>. The CHARMS Phase 2 Study was based on positive preliminary results in a similar Phase 1/Phase 2a study that initially began in 2012. *See* [clinicaltrials.gov/study/NCT01570283](https://clinicaltrials.gov/study/NCT01570283).

39. On December 13, 2021, AlloVir disclosed results from the CHARMS Phase 2 Study of posoleucel. AlloVir disclosed multiple rounds of preliminary results from the CHARMS Phase 2 Study prior to the Class Period, before publishing final results in January 2023. *See* <https://pubmed.ncbi.nlm.nih.gov/36628536/>. The Company reported that in the CHARMS Phase 2 Study, 95% of allogeneic HCT patients with infections from one or more of the target viruses

and who previously failed or were intolerant to conventional antiviral treatments, achieved a clinical response when treated with posoleucel therapy.

40. Posoleucel was also in a Phase 2 study of posoleucel for its efficacy as a treatment for BK viremia in kidney transplant patients. *See* <https://clinicaltrials.gov/study/NCT04605484>. This study was completed in 2022 and AlloVir reported positive results in February 2023. The Company represented that the data shows “balanced safety across posoleucel and placebo groups and clinically meaningful greater viral load declines with posoleucel versus placebo.” *See* February 15, 2023 press release titled “AlloVir Reports Full-Year 2022 Financial Results and 2023 Outlook.”

41. Posoleucel was also the subject of a Phase 2 study related to its efficacy for multi-virus prevention (the “MVP Phase 2 Study”). Prior to the Class Period, on March 22, 2022, AlloVir reported that initial results from the MVP Phase 2 Study were overwhelmingly positive. Specifically, the Company stated that, “[o]ut of 26 patients who received at least one dose of posoleucel …only three clinically significant infections were observed through Week 14, as of the data cut-off for this analysis. Of the 24 patients who have reached the Week 14 primary endpoint, 21 remained free of clinically significant infections.” The Company relied on these initial positive results from the MVP Phase 2 Study to justify the initiation of the MVP Phase 3 Trial. Additionally, during the Class Period, on April 26, 2023, AlloVir provided an update on the MVP Phase 2 Study and represented that “positive long-term, follow-up data from the [MVP] Phase 2 [S]tudy…demonstrate[s] that the high-risk allo-HCT patients who received posoleucel experienced continued low rates of clinically significant infections and end-organ disease and 0% non-relapse mortality.”

**C. Defendants Concealed That Posoleucel's Three Phase 3 Clinical Trials Were Futile Based on the DSMB Recommendations During the Class Period**

42. During the Class Period, AlloVir's lead product posoleucel was in three ongoing different Phase 3 trials for different applications. One of the Phase 3 trials related to posoleucel's efficacy for the prevention of the six target viruses (the MVP Phase 3 Trial). The other two Phase 3 trials related the posoleucel's efficacy for the treatment of certain of the six target viruses and complications related to those viruses (the ADV Phase 3 Trial and VHC Phase 3 Trial).

43. As the sponsor of the three Phase 3 Trials, AlloVir was responsible for the design of the Trials, the study protocols, and statistical analysis plans.

44. AlloVir instituted a DSMB for each of the Phase 3 Trials.

45. AlloVir directed the DSMB for each of the Trials to make recommendations to the Company on study continuation.

46. The design of each of the Trials required an independent DSMB to perform a futility analysis early on in the Trials, *i.e.*, when a certain number of participants in the trial reached the primary endpoint, the DSMB analyzes the early results to determine whether it is even possible for the trial to show the product is safe and effective. If there was no longer a likelihood of the trial showing the product is safe and effective, make a recommendation to AlloVir to terminate the trial to conserve resources for the Company and to protect patients from further exposure to a potentially ineffective investigational product.

**1. The MVP Phase 3 Trial Was Futile by at Least January 10, 2023**

47. One of AlloVir's Phase 3 Trials of posoleucel was the MVP Phase 3 Trial. The full name of this trial was "Study of Posoleucel (ALVR105, Viralym-M) for Multi-Virus Prevention in Patients Post-Allogeneic Hematopoietic Cell Transplant (Prevent)." See <https://clinicaltrials.gov/study/NCT05305040>.

48. AlloVir first announced the initiation of the MVP Phase 3 Trial on March 22, 2022. The Company’s announcement that it was proceeding to a Phase 3 Trial for this use of posoleucel was based on what the Company described as initial data from the MVP Phase 2 Study that supported the expansion into a Phase 3 Trial.

49. AlloVir designed the MVP Phase 3 Trial as a randomized, double-blind, placebo controlled trial.<sup>2</sup>

50. The Company anticipated approximately 302 enrollees in the MVP Phase 3 Trial.

51. The primary endpoint of the MVP Phase 3 Trial was the “Average Number of Clinically Significant Infections or Episodes of End-Organ Disease Through Week 14.”

52. On December 6, 2023, AlloVir updated the MVP Phase 3 Trial by delaying the estimated primary completion date to December 30, 2024 from September 30, 2024. The Company also updated the status of the MVP Phase 3 Trial to reflect that the trial had over-enrolled—there were 377 participants enrolled, rather than the 302 participants that were initially anticipated. See <https://clinicaltrials.gov/study/NCT05305040?tab=history>.

53. AlloVir officially terminated the MVP Phase 3 Trial on December 22, 2023.

54. On April 19, 2024, after announcing that the MVP Phase 3 Trial was terminated, AlloVir submitted results to the FDA. The results of the MVP Phase 3 Trial became publicly available on the Clinical Trials Website on May 16, 2024. At this time, the Study Protocol (“MVP SP”) and Statistical Analysis Plan (“MVP SAP”) documents, which were known internally to Defendants during the Class Period, became publicly available for the first time.

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<sup>2</sup> The MVP Phase 2 Study, which AlloVir designed as “open label,” was also ongoing during the same period. See <https://clinicaltrials.gov/study/NCT04693637>

55. The original version of the MVP SP is dated July 13, 2020. The MVP SP notes that AlloVir made seven amendments to the MVP SP between July 13, 2020 and May 1, 2023. AlloVir uploaded the operative version of the MVP SP to the Clinical Trials Website after the end of the Class Period, on April 19, 2024. See [https://cdn.clinicaltrials.gov/large-docs/40/NCT05305040/Prot\\_000.pdf](https://cdn.clinicaltrials.gov/large-docs/40/NCT05305040/Prot_000.pdf).

56. The operative version 1 of the MVP SAP is dated June 22, 2023. The MVP SAP was signed by representatives of AlloVir. The MVP SAP was uploaded to the Clinical Trials Website after the end of the Class Period, on April 19, 2024. See [https://cdn.clinicaltrials.gov/large-docs/40/NCT05305040/SAP\\_001.pdf](https://cdn.clinicaltrials.gov/large-docs/40/NCT05305040/SAP_001.pdf).

57. The MVP SP states, “Approximately 302 patients in the Phase 3 study cohort will then be dosed with posoleucel or placebo at a 1:1 ratio. **A futility analysis and sample size re-estimation (SSRE) will be conducted, the details of which will be described separately.** Based on a planned interim sample size re-estimation (SSRE) analysis, approximately 125 additional patients may be dosed in Phase 3.” MVP SP at 31.

58. The MVP SAP states that:

**A formal interim futility analysis and a sample size re-estimation (SSRE) based on the primary efficacy endpoint will be conducted after the first 121 subjects have completed Week 14 or discontinued prior to Week 14, which is 40% of the planned sample size of 302 subjects... The decision to stop for futility is based on the conditional probability that the study will be successful at the time of final analysis, assuming the current trend observed at the interim. If, at the interim analysis, the conditional probability of study success with 302 mITT Population falls below 10%, the study may stop early for futility. Enrollment and patient follow-up will then be discontinued, and the final analyses will be conducted.** The futility stopping in this study is considered non-binding.” MVP SAP at 12.

59. The MVP SP states that, “In Phase 3, the DSMB will assess safety on an ongoing basis and will make recommendations on study continuation.” MVP SP at 61.

60. The MVP SP also states that, “the DSMB will meet throughout the study as indicated in the DSMB charter (see DSMB charter).” MVP SP at 63.

61. The results from the MVP Phase 3 Trial were made publicly available on the Clinical Trials Website on May 16, 2024. The MVP Phase 3 Trial results state that the trial enrolled 377 patients in the 89-week period from March 22, 2022 to December 6, 2023. This amounts to 4-5 new patients enrolled per week.

62. The MVP Phase 3 Trial began on March 22, 2022, and with an enrollment of 4-5 patients per week, the MVP Phase 3 Trial reached enrollment of 121 patients by approximately, October 4, 2022. The week 14 primary endpoint would have been completed for these 121 patients by January 10, 2023. Therefore, the DSMB performed its futility analysis, finding that proceeding with the MVP Phase 3 Trial for FDA approval of posoleucel was futile, by January 10, 2023. The DSMB’s recommendation to the Company at this time would have been that the MVP Phase 3 Trial’s continuation was futile.

63. The Company failed to report during the Class Period that the DSMB found that proceeding with MVP Phase 3 Trial was futile.

## **2. The VHC Phase 3 Trial Was Futile by at Least September 2, 2023**

64. Posoleucel was also in a Phase 3 trial for the treatment of VHC and VHC related complications in Allo-HCT patients. The full title of the VHC Phase 3 Trial was “Phase 3 Multicenter, Double-Blind, Placebo-Controlled Trial of Viralym-M (ALVR105) for the Treatment of Patients With Virus-Associated Hemorrhagic Cystitis After Allogeneic Hematopoietic Cell Transplant (HCT).” See <https://clinicaltrials.gov/study/NCT04390113>.

65. AlloVir first submitted the VHC Phase 3 Trial to the FDA on May 12, 2020. On January 6, 2021, AlloVir updated the VHC Phase 3 Trial to reflect that its status had changed to

“Recruiting.” AlloVir later updated the VHC Phase 3 Trial to reflect that the actual start date was March 18, 2021.

66. AlloVir designed the VHC Phase 3 Trial as a randomized, multicenter, double-blind, placebo-controlled study.

67. The estimated study completion date for the VHC Phase 3 Trial was set for August 15, 2022.

68. The primary endpoint of the VHC Phase 3 Trial was the time until urine is visually clear of hematuria. This was measured in a time frame of 24 weeks from the start of the study.

69. On December 20, 2021, AlloVir updated the VHC Phase 3 Trial to change the estimated study completion date to June 30, 2023 from August 15, 2022.

70. AlloVir officially terminated the VHC Phase 3 Trial on December 22, 2023.

71. On April 18, 2024, AlloVir submitted results from the VHC Phase 3 Trial to the FDA. The results were made publicly available on the Clinical Trials Website on May 8, 2024. At this time, the Study Protocol (“VHC SP”) and Statistical Analysis Plan (“VHC SAP”) documents, which were known internally to Defendants during the Class Period, became publicly available for the first time.

72. The original version of the VHC SP is dated December 26, 2019. The VHC SP notes that AlloVir made four amendments to the VHC SP between December 19, 2019 and February 23, 2022. AlloVir uploaded the operative version of the VHC SP to the Clinical Trials Website after the end of the Class Period, on April 18, 2024. *See* [https://cdn.clinicaltrials.gov/large-docs/13/NCT04390113/Prot\\_000.pdf](https://cdn.clinicaltrials.gov/large-docs/13/NCT04390113/Prot_000.pdf).

73. The operative version 1 of the VHC SAP is dated November 14, 2023. The VHC SAP was signed by representatives of AlloVir, namely the Vice President, Biostatistician of

AlloVir and the Senior Director, Clinical Research of AlloVir. The VHC SAP was uploaded to the FDA clinical trials website after the end of the Class Period, on April 18, 2024. See [https://cdn.clinicaltrials.gov/large-docs/13/NCT04390113/SAP\\_001.pdf](https://cdn.clinicaltrials.gov/large-docs/13/NCT04390113/SAP_001.pdf).

74. The VHC SP states “[a]n interim analysis will be conducted by an independent unblinded statistician and reviewed by the independent DSMB. This analysis will be based on primary efficacy endpoint data for the first 60 participants randomized in the BK ITT Population. The interim analysis will be for purposes of potentially stopping early for success and for futility.” VHC Study Protocol at 67.

75. The VHC SP also states that:

**The interim analysis for futility will also be based on the primary efficacy endpoint.** The decision to stop for futility is based on the conditional probability that the study will be successful should it continue to the sample size of 105 participants in the BK ITT Population with participants being followed for 24 weeks. The calculation will assume that the final analysis will be a log-rank test conducted at the one-sided 0.0147 level. If, at the interim analysis, the conditional probability of study success with 105 BK ITT Population participants falls below 5%, the study will stop early for futility. Enrollment and participant follow-up will then be discontinued, and the final analyses will be conducted. The futility stopping in this study is considered non-binding.

VHC SP at 67-68.

76. The VHC SAP states that:

**An interim analysis will be conducted by an independent unblinded statistician and reviewed by the independent DSMB. This analysis will be based on primary efficacy endpoint data for the first approximately 60 participants randomized in the BK ITT Population.** The interim analysis will be performed for the purpose of potentially stopping early for futility (VHC SP at 67). ... **The interim analysis for stopping early for futility will be based on the primary efficacy endpoint.** The decision to stop for futility is based on the conditional probability that the study will be successful, assuming the current trend observed at the interim, should it continue to the sample size of 105 participants in the BK ITT Population with participants being followed for 24 weeks. The calculation will assume that the final analysis will be a log-rank test with overall alpha = 0.025 (one-sided) adjusted for the interim analysis. If, at the interim analysis, the conditional probability of study success with 105 BK ITT Population participants falls below 5%, the study will stop early for futility (Lachin 2005).

VHC SAP at 26-27.

77. The VHC SAP also states that the DSMB will “routinely monitor safety and evaluate prespecified interim analyses to stop the study early for futility.” VHC SAP at 9, 26.

78. The results from the VHC Phase 3 Trial were made publicly available on the Clinical Trials Website on May 8, 2024. The VHC Phase 3 Trial results state that the trial enrolled 97 patients in the 33-month period from March 18, 2021 to December 22, 2023. This amounts to 2-3 patients enrolled per month. *See* <https://clinicaltrials.gov/study/NCT04390113>.

79. The VHC Phase 3 Trial began on March 18, 2021, and with an enrollment of 2-3 patients per month, the VHC Phase 3 Trial reached 60 patients enrolled in 24 months or less, by at least March 18, 2023. The week 24 primary endpoint for these 60 patients would have been reached by at least September 2, 2023. The DSMB performed its futility analysis at that time, finding that proceeding with the VHC Phase 3 Trial for FDA approval of posoleucel was futile, by September 2, 2023. The DSMB’s recommendation to the Company at this time would have been that the VHC Phase 3 Trial’s continuation was futile.

80. AlloVir failed to report during the Class period that the DSMB found that proceeding with the VHC Phase 3 Trial was futile.

### **3. The ADV Phase 3 Trial Was Futile by at Least October 10, 2023**

81. AlloVir’s lead product posoleucel was also in Phase 3 Trial for the treatment of adenovirus. The full name of the ADV Phase 3 Trial was “Posoleucel (ALVR105) for the Treatment of Adenovirus Infection in Pediatric and Adult Participants Receiving Standard of Care Following Allogeneic Hematopoietic Cell Transplantation.” *See* <https://clinicaltrials.gov/study/NCT05179057>.

82. AlloVir first submitted the ADV Phase 3 Trial to the FDA on December 17, 2021. AlloVir later updated the ADV Phase 3 Trial to reflect that the actual start date was May 11, 2022.

83. AlloVir designed the ADV Phase 3 Trial as a multicenter, randomized, double-blind, placebo-controlled study.

84. AlloVir officially terminated the ADV Phase 3 Trial on December 22, 2023.

85. On April 15, 2024, after announcing that the ADV Phase 3 Trial was terminated, AlloVir submitted results to the FDA. The results became publicly available on the Clinical Trials Website on May 8, 2024. At this time, the Study Protocol (the “ADV SP”) and Statistical Analysis Plan (the “ADV SAP”) documents, which were known internally to Defendants during the Class Period, became publicly available for the first time.

86. The original version of the ADV SP is dated August 20, 2021. The ADV SP notes that AlloVir made four amendments to the ADV SP between August 20, 2021 and November 30, 2023. The operative Amendment 4, Version 5 of the ADV SP is dated November 30, 2023. The ADV SP is signed by representatives for AlloVir. AlloVir uploaded the operative version of the ADV SP to the Clinical Trials Website after the end of the Class Period, on April 15, 2024. *See* [https://cdn.clinicaltrials.gov/large-docs/57/NCT05179057/Prot\\_000.pdf](https://cdn.clinicaltrials.gov/large-docs/57/NCT05179057/Prot_000.pdf).

87. The operative version 1 of the ADV SAP is dated January 12, 2024. The ADV SAP is signed by representatives for AlloVir. AlloVir uploaded the ADV SAP to the Clinical Trials Website after the end of the Class Period, on April 15, 2024. *See* [https://cdn.clinicaltrials.gov/large-docs/57/NCT05179057/SAP\\_001.pdf](https://cdn.clinicaltrials.gov/large-docs/57/NCT05179057/SAP_001.pdf).

88. The ADV SP states that, “[a]n independent Data and Safety Monitoring Board (DSMB) will be convened for this study to routinely monitor participant safety and evaluate prespecified interim analyses for futility and sample size re-estimation (SSRE).” ADV SP at 16, 71.

89. The ADV SP provides that:

**A sample size re-estimation (SSRE) and a futility analysis will be performed after approximately 40 participants have completed Day 29 of the Primary Study Period.** The SSRE will be based on the conditional power (CP), ie, the conditional probability of rejecting the null hypothesis, using the method of Mehta and Pocock (2010) for a CP of 80%. For the futility analysis, a CP cutoff of 10% will be applied. The interim analyses (SSRE and futility analysis) will both be conducted in a manner so as to minimize the risk of operational bias. It will be done under the auspices of the independent DSMB overseeing the study. The analyses will be performed by an independent statistician. The unblinded data generated and discussed by the DSMB for the interim analyses will be kept confidential. In particular, the information will not be accessible to the investigators and site staff, the Sponsor's team and medical monitor, and CRO blinded team members, or the Adjudication Committee. ADV SP at 63.

90. Appendix 10 to the ADV SP provides a history of amendments to the ADV SP. The “Amendment 3 Rationale” states that “[g]iven the limited population of allo-HCT that develop clinically significant AdV infection, enrollment into this trial is approximately 2-3 patients per month.” ADV SAP at Appendix 10, 96-97.

91. The ADV Phase 3 Trial began on May 11, 2022 and with enrollment at approximately 2-3 patients per month, the ADV Phase 3 Trial reached an enrollment of 40 patients by approximately September 11, 2023, and these patients would have completed Day 29 by October 10, 2023. Even using conservative estimates, the DSMB performed its futility analysis, finding that proceeding with the ADV Phase 3 Trial for FDA approval of posoleucel was futile, by at least October 10, 2023. The DSMB’s recommendation to the Company at this time would have been that the ADV Phase 3 Trial’s continuation was futile.

92. AlloVir failed to report during the Class Period that the DSMB found that proceeding with the ADV Phase 3 Trial was futile.

#### **D. Defendants Tout Posoleucel’s Efficacy While Failing to Disclose They Already Knew That Proceeding with the Phase 3 Trials Was Futile**

93. Throughout the Class Period, Defendants repeatedly touted posoleucel’s efficacy based on outdated Phase 2 results and guided investors to believe that posoleucel had the potential

to provide AlloVir with a commercially viable product by representing that the Trials were ongoing and continuing to enroll patients.

94. Even in November 2023, well after determining that proceeding with the commercial development of posoleucel for multi-virus prevention or treatment of VHC and ADV was futile, AlloVir claimed that the Trials would continue with results from “all three trials in the second half of 2024.”

**E. Defendants Reveal That It Was Futile to Continue the Three Phase 3 Trials for Posoleucel**

95. On December 22, 2023 Defendants shocked the market by issuing a press release and filing a corresponding Form 8-K with the SEC stating that all three of the Phase 3 trials were to be terminated, effective immediately.

96. The Company stated that it “made the determination following three pre-planned analyses by three independent Data Safety Monitoring Boards (DSMBs) each of which recommended stopping its respective trial for futility after a review of the data suggested that each study was unlikely to meet its primary endpoint.”

97. On this news shares of AlloVir plummeted \$1.57 per share, or 67.38%, to close at \$0.76 per share on December 22, 2023.

**F. Analysts Were Surprised That AlloVir Terminated the Trials on the DSMBs’ Recommendations and AlloVir Collapses**

98. Analysts were stunned to learn that all three Phase 3 trials for posoleucel were abruptly being terminated on the recommendations of the DSMBs.

99. A December 22, 2023 analyst report from Piper Sandler by Christopher J. Raymond, Allison M. Bratzel, CFA and Nicole A. Gabreski, PhD and titled “Downgrade to Neutral; *This One Really Came Out of Left Field*” expressed how surprising this news was:

Stepping to the sidelines on ALVR shares after the shocking decision to discontinue development of posoleucel in all indications. *Unbeknownst to us, management had planned futility analyses of all three P3 studies of posoleucel* (multi-virus prevention, treatment of vHC and treatment of adenovirus infections in allo-HSCT patients). While the timing is surprising, even more surprising to us is the outcome, given all the data produced with this therapy to date.

...

Surprising - on a couple of levels. With the compendium of data to date, including PoC demonstrated in the P2 CHARMS study (multi-virus treatment) and more recent PoC from the P2 multi-virus prevention study, *today's news comes as a surprise to us just on the basis of clinical data. That said, we are doubly surprised in that it was never disclosed that these trials had planned futility analyses baked into their design, let alone the timing.*

100. A December 22, 2023 JP Morgan analyst report by Anupam Rama, Malcolm A. Kuno, and Priyanka Grover, PhD and titled “Moving to Underweight; Posoleucel Pivotal Trials Discontinued” similarly stated:

AlloVir announced the discontinuation of all 3 ongoing pivotal trials of lead asset posoleucel (prevention, treatment of virus-associated hemorrhagic cystitis, and adenovirus), following DSMB recommendation to stop studies for futility. *This is, of course, a disappointing and surprising outcome given what we had considered to be de-risking mid-stage data for the product.* Based on our discussion with the company, while evaluation of the data will occur from the 3 trials, our sense is that moving forward with the solid organ transplant setting is off the table as well.

101. On January 4, 2024, AlloVir filed a Form 8-K with the SEC reporting that, in light of the termination of the three Phase 3 Trials, the Company would layoff nearly all of its approximately 100 employees, stating “[o]n January 1, 2024, the board of directors of AlloVir [] approved a reduction of its workforce by approximately 95% of AlloVir’s current employee base.”

## V. DEFENDANTS’ MISLEADING STATEMENTS AND MATERIAL OMISSIONS

### A. January 10, 2023 Presentation at J.P. Morgan Healthcare Conference Presentation

102. On January 10, 2023, Defendant Brainard participated in the J.P. Morgan Healthcare Conference on behalf of AlloVir (the “J.P. Morgan Presentation”). At the conference

she gave a presentation titled “Allogeneic, Off-the-Shelf, Virus-Specific T Cell Therapies in Late-Stage Development.”

103. Defendant Brainard’s J.P. Morgan Presentation included slides providing information about AlloVir’s three Phase 3 Trials and the positive results from the MVP Phase 2 Study and CHARMS Phase 2 Study. The slides stated:

3 ongoing global Phase 3 registrational trials for 3 first-to-market indications expected to complete enrollment in 2023

– Large and critically important unmet need: preventing or treating clinically significant viral infections post transplant

– Multi-virus prevention strategy has potential to transform the transplant space

• Compelling Phase 2 trial results presented at ASH 2021 and 2022

• High need and strong support from transplant and infectious disease communities

• Robust enrollment in Phase 3 trial in 2022 accelerates timing for trial completion and data readout

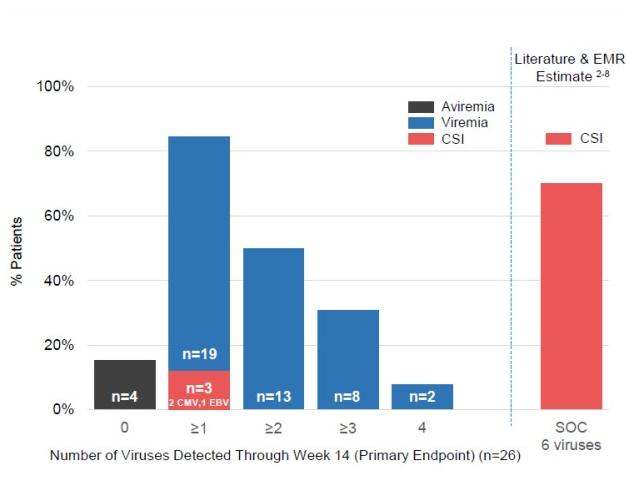
....

“Multi-VST therapy in Phase 3 development for 3 indications”

....

“Phase 2 data demonstrate promising efficacy … in both treatment and prevention settings”

## Final Open-Label Phase 2 Prevention Study Results Demonstrate Low Rates of Clinically Significant Infection<sup>1</sup>



### Low Rates of Clinically Significant Infection

- 23/26 (88%) patients CSI-free through Week 14
- 22/26 (85%) patients reactivated ≥1 target virus

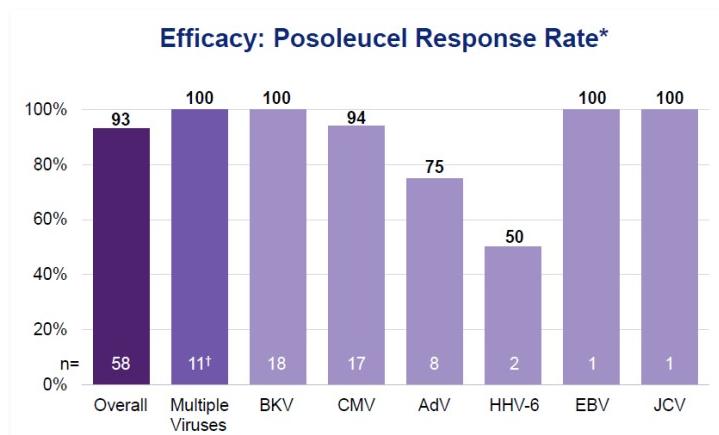
### Repeat Dosing Generally Well Tolerated

- No unanticipated TEAEs or SAEs
- 5 cases (19%) of acute GVHD (grades II-IV)

### Biomarker Data Support Mode of Action

- VST cell expansion coincident with viral load declines
- Presence of posoleucel confirmed during and after infusion period

## Phase 2 CHARMS Treatment Study Demonstrated 93% Efficacy In Treatment-Refractory Patients<sup>1,2</sup>



### Safety: Posoleucel Well Tolerated

- Infusions were well tolerated
  - n=3 developed isolated fever within 24 hours of infusion; no immediate toxicities observed
- 14 cases of acute GVHD
  - n=8 had pre-existing GVHD
  - n=6 de novo GVHD; all had transient Grade I skin GVHD resolved with treatment
- No cytokine release syndrome

CR = Viral load return to normal range and resolution of clinical signs/symptoms  
PR = ≥50% decrease in viral load and/or 50% improvement of clinical signs/symptoms



\*Response rate / patient includes partial response (PR) or complete response (CR) by 6 weeks post-posoleucel infusion; 11/11 patients had a response to ≥1 virus(es) and 19 of 23 viruses across the 11 patients responded to posoleucel. †. Tzannou I, et al. J Clin Oncol 2017;35:3547-57; 2. Tzannou I, et al. ASH 2020. Accessed January 4, 2021. <https://ash.confex.com/ash/2020/webprogram/Paper143037.html>.

104. The January 10, 2023 statements in paragraph 103 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, while repeating the positive results from the Phase 2 studies, which were

misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

105. During the J.P. Morgan Presentation, Defendant Brainard made statements regarding the viability of and enrollment in the Phase 3 Trials. Specifically, Defendant Brainard stated:

So posoleucel, which is our lead virus-specific T cell investigational therapy, targets 6 different viruses, and as such, it's a franchise opportunity in immunocompromised patients. We're starting off in stem cell transplant recipients where, as I mentioned, we have 3 Phase III ongoing global registrational trials for first-to-market indications in treatment and in prevention. We're addressing really large and unmet medical needs across immunocompromised patients, looking at prevention and treatment supported by our Phase II data. And what we've seen over the last year with the pace of enrollment across our trials is that this is really speaking to the unmet need we're addressing and the fact that both the infectious disease and transplant community are looking for options because they've had none so far or those with limited safety and tolerability.

We recently communicated on Monday in our press release that we're targeting now to finish enrollment of our 3 Phase III trials by the end of this year, which puts us in a great position to have data rolling out over the course of 2024.

106. These January 10, 2023 statements in paragraph 105 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, while repeating the positive results from the Phase 2 studies, which were

misleading because Defendant Brainard omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

107. At the J.P. Morgan Presentation, Defendant Brainard provided descriptions of the ongoing Phase 3 Trials and explained that:

You can see our pipeline here on Slide 5. With posoleucel listed at the top, our 3 Phase III ongoing global trials, multi-virus prevention study, the 2 treatment studies, 1 in virus-associated hemorrhagic cystitis, 1 in adenovirus infection, all of these studies are on track to complete enrollment this year. And we're excited about that because we just started the multi-virus prevention study earlier in 2022 based on compelling Phase II data. And we wanted to prioritize that trial because of the tremendous impact we could have in the stem cell transplant space for patients by taking a preventative approach. And what we've seen is tremendous success pulling in our learnings from the treatment studies and getting that study off the ground in North America, Europe and Asia, enrolling such that we've been able to pull in our time lines by over a quarter and target being on track to finish that trial by the end of the year.

108. The January 10, 2023 statements in paragraph 107 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and on track to finish by the end of 2023, while repeating the positive results from the MVP Phase 2 Study, which was misleading because Defendant Brainard omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA

approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

109. During the J.P. Morgan Presentation, Defendant Brainard emphasized the preliminary results from the MVP Phase 2 Study:

"So I'm going to turn now to a little bit of data, starting again with the Phase II prevention data. We presented final data from our Phase II open-label study in December of ASH in 2022, just last month. These data were presented orally, and we're very consistent with the data that we had presented a year earlier with a slightly smaller database and shorter time of follow-up. And it was really important for us to demonstrate the consistency of the efficacy and the safety with a larger patient population and longer follow-up. And what you can see here is that this is a high-risk patient population of allo patients. The 85% of patients reactivated at least a single virus or more viruses during the 14-week time period to the primary end point. So lots of viral reactivation as you would expect in this high-risk patient population. But we did not see significant rates of clinically significant infections. So 88% or 23 of 26 patients remained free from clinically significant infections across all 6 target viruses through the primary end points. We don't have a control arm in this trial, so we look to the literature and to claims analyses to try to understand what that expected control rate could be. **And what we've seen is that we would expect about a 70% rate of infections across these 6 target infections. And so that difference was what enabled us to get into Phase III as quickly as we did and what gives us a lot of excitement and confidence, which we also feel is shared by the community given the pace of enrollment of the Phase III trial.**

....

And what you can see here is with 1 or 2 doses of posoleucel in general, very high clinical response rates to across all of these different viruses. So 93% overall response rate. Importantly, there were a number of patients who had multiple viral infections at the same time. They had response rates of 100% to these multiple viral infections. Safety, the infusions were well tolerated with rates of graft versus host disease that would be expected and consistent with what the field has understood around VST's no significant cytokine release syndrome. So these were the treatment data that propelled us into Phase III on the viral hemorrhagic cystitis study and the adenovirus treatment study, 2 diseases, which have no approved therapies and really substantial unmet need.

110. The January 10, 2023 statements in paragraph 109 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, while repeating the positive results from the MVP Phase 2 Study, which were misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

111. During the J.P. Morgan Presentation Anupam Rama, JPMorgan Chase & Co, Research Division - VP and Analyst asked Defendant Brainard about the risk factor posed by these trials to the Company:

Q: When you think about the adeno and virus-associated hemorrhagic cystitis cohorts specifically, how do those data derisk the 2 pivots?

....

A.: And so the clinical data that supports virus-associated hemorrhagic cystitis was presented at the TCT conference in 2021 and looked at the subset of patients with BK virus-associated hemorrhagic cystitis, looking at the time to resolution of macroscopic hematuria, which is our primary end point in the Phase III trial, and comparing it to a matched cohort from Texas Children's Hospital and showing a substantial difference in the time to resolution. Those natural history data have now been further corroborated by a natural history cohort at MD Anderson, which is a nice way for us to confirm our powering. But this is a – **that's for the virus-associated hemorrhagic cystitis where we feel there is a reason to believe we're well situated for a positive outcome there.**

112. The January 10, 2023 statements in paragraph 111 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product

for AlloVir, representing that the VHC Phase 3 Trial was ongoing, while repeating the positive results from the Phase 2 studies, which was misleading because Defendant Brainard omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

#### **B. February 15, 2023 Press Release and 2022 Financial Results**

113. On February 15, 2023, the Company published a press release announcing its full year 2022 financial results. The Press release was titled: "AlloVir Reports Full-Year 2022 Financial Results and 2023 Outlook." The Company's February 15, 2023 press release stated:

**Completion of enrollment of all three posoleucel Phase 3 registrational trials for three distinct, first-to-market indications anticipated by end of 2023 and data readouts in 2024**

....

"With the acceleration of the posoleucel multi-virus prevention study and continued enrollment in the viral hemorrhagic cystitis and adenovirus treatment Phase 3 studies in 2022, **the posoleucel franchise is positioned for potentially significant value creation over the next 12-24 months,**" said Diana Brainard, M.D., Chief Executive Officer, AlloVir. "During 2023, we plan to complete enrollment in our Phase 3 registrational studies, **which would enable data readouts in 2024 and, with positive results, regulatory filings and acceleration of commercial preparations to follow.**"

....

In an oral presentation at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022, final data were presented from the

Phase 2 study evaluating posoleucel for the prevention of clinically significant infections or diseases from adenovirus, BK virus, cytomegalovirus, Epstein-Barr virus, human herpesvirus-6 and JC virus in allo-HCT patients. **The data demonstrated a substantial reduction in the expected rate of clinically significant viral infections in this high-risk patient population despite the expected high rates of viral reactivation observed.** Biomarker data showed the persistence of posoleucel and association between expansion of functional VSTs and viral control.

....

In January 2023, final data from the CHARMS Phase 2 study of posoleucel for the treatment of viral infections in treatment-refractory allo-HCT patients were published in Clinical Cancer Research. **The data demonstrated that 95% of patients with one or more treatment-refractory infections achieved a clinical response with posoleucel.**

....

The posoleucel Phase 3 multi-virus prevention trial is enrolling adult and pediatric patients globally. Enrollment is expected to complete by year-end 2023, **enabling topline data in mid-2024.** Global enrollment is ongoing in Phase 3 studies of posoleucel for the treatment of virus-associated hemorrhagic cystitis and adenovirus infection, both in adult and pediatric allo-HCT patients. **Both studies are expected to complete enrollment by year-end 2023, with topline data anticipated in 2024.**

114. The February 15, 2023 statements in paragraph 113 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 trials were ongoing and data readouts were expected in 2024, that “the posoleucel franchise is positioned for potentially significant value creation,” while repeating the positive results from the MVP Phase 2 Study and CHARMS Phase 2 Study, which were misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on

the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.

115. On February 15, 2023, the Company filed its Form 10-K with fiscal year 2022 financial results with the SEC (the "2022 10-K"). The 2022 10-K was signed by the Individual Defendants and stated:

Posoleucel is being studied in three ongoing Phase 3 registrational trials for 3 distinct indications - the prevention of clinically significant infections from multiple viruses, the treatment of virus-associated hemorrhagic cystitis, or HC, and the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel. We have successfully accelerated the multi-prevention study in recognition of the fact that prevention best addresses patients' unmet medical needs. The three Phase 3 studies are expected to complete enrollment by the end of 2023, enabling potential data readouts from all three trials in 2024. The three registrational trials were informed by the positive results of proof-of-concept studies with posoleucel for both treatment and prevention. In the CHARMS Phase 2 treatment trial, 95% of allogeneic HCT patients with one or more treatment-refractory infections achieved a clinical response with posoleucel. In the Phase 2 multi-virus prevention trial, posoleucel demonstrated a substantial reduction in the expected rate of clinically significant viral infections or diseases, with 88% of patients remaining free of clinically significant infections caused by any of the six viruses that posoleucel targets through the Week 14 primary endpoint.

116. The February 15, 2023 statements in paragraph 115 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, while repeating the positive results from the MVP Phase 2 Study and CHARMS Phase 2 Study, which were misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on

the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.

### **C. April 26, 2023 Press Release and Presentation**

117. On April 26, 2023 AlloVir issued a press release titled "AlloVir Announces Positive Results Including Long-Term Mortality Data in Phase 2 Posoleucel Multi-Virus Prevention Study in Oral Presentation at EBMT 2023."

118. The Company's April 26, 2023 press release stated that the key takeaways from the MVP Phase 2 Study data were:

Day 400 non-relapse mortality was 0%

Previously reported data from the 14-week primary endpoint showed low rates of clinically significant viral infections and diseases in this high-risk patient population despite the expected high rates of viral reactivation

Global Phase 3 pivotal posoleucel trials continue to progress with robust patient enrollment in the US, Europe and Asia with data readouts on track for 2024

119. The April 26, 2023 statements in paragraph 118 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were progressing and data readouts were expected in 2024, while repeating the positive results from the MVP Phase 2 Study, which were misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that

continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

120. The April 26, 2023 press release further stated that:

The data presented today provide further evidence supporting the potential benefits of using posoleucel to prevent viral infection in high-risk allo-HCT patients. The non-relapse mortality rate in patients receiving posoleucel was 0% through week 52 which compares favorably with published non-relapse mortality rates among allo-HCT patients ranging from 9 percent to over 15 percent,” said Diana Brainard, MD, CEO, AlloVir. “Our global, registrational Phase 3 clinical trial further exploring the potential of posoleucel for multi-virus prevention is well underway and we anticipate data from this registrational study in 2024. If successful, an option that prevents viral infection, such as posoleucel, could transform the care of allo-HCT patients.

121. The April 26, 2023 statement in paragraph 120 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were “well underway” and data readouts were expected in 2024, while repeating the positive results from the MVP Phase 2 Study, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB’s analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

122. The April 26, 2023 press release explained that investors should review the Clinical Trials Website for further information about the MVP Phase 3 Trial of posoleucel while also continuing to tout the positive results from the MVP Phase 2 Study.

Details from the [posoleucel] Phase 2 study were reported in December 2022 and can be found here. The study also included a 52-week follow-up visit, data from which were presented today at EBMT. These new data demonstrate that, of the 26 patients dosed with posoleucel, the five deaths were all related to relapse/progression of underlying disease; none were due to infection or deemed treatment-related, resulting in 0% non-relapse mortality. More information on the ongoing, global, registrational, Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trial of posoleucel for multi-virus prevention can be found on clinicaltrials.gov under the study ID (NCT05305040).

123. The April 26, 2023 statements in paragraph 122 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the MVP Phase 3 Trial was ongoing, while repeating the positive results from the MVP Phase 2 Study, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.

124. On April 26, 2023, the Company published the presentation it gave at the EBMT 2023 conference making additional representations regarding the latest results from the MVP Phase 2 Study. The presentation is titled "Final Clinical and Biomarker Data from a Phase 2 Trial of Posoleucel, an Off-the-shelf, Multivirus-specific T Cell Therapy, for Prevention of Clinically Significant Viral Infections Post-HCT." The presentation is posted on the Company's website with the title: "EBMT 2023 Prevent OL 04-25-23\_FINAL.pdf" (the "EBMT Presentation").

125. The slides published in connection with the Company's EBMT Presentation repeatedly touted the efficacy demonstrated in MVP Phase 2 Study. The slides stated that there were "low rates of clinically significant infections through week 14," and that there was a "0% day 400 non-relapse mortality and no infection related mortality."

126. The April 26, 2023 statements in paragraph 125 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, while repeating the positive results from the MVP Phase 2 Study, which were misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.

#### **D. May 4, 2023 Press Release and Second Quarter 2023 Financial Results**

127. On May 4, 2023 AlloVir issued a press release announcing its first quarter 2023 financial results.

128. The first line of the May 4, 2023 press release stated: "Company's three posoleucel Phase 3 global registrational trials for three distinct, first-to-market indications continue to enroll with data readouts on track for 2024."

129. The May 4, 2023 statements in paragraph 128 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were

expected in 2024, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.

130. The Company's May 4, 2023 press release stated:

We continue to focus our efforts on rapidly advancing the three global Phase 3 ongoing registrational trials evaluating our lead investigational product, posoleucel, for the prevention and treatment of common, yet devastating, and potentially life-threatening viral infections and diseases in allo-HCT patients where significant unmet need persists," said Diana Brainard, MD, Chief Executive Officer, AlloVir. "In tandem, we reported final positive results from the Phase 2 study of posoleucel for the treatment of BKV, the first demonstration of its safety and antiviral effect in solid organ transplant recipients. We continue to be encouraged by the potential of posoleucel as a transformative therapeutic for transplant patients.

....

In January 2023, the company announced plans to report data from its three Phase 3 registrational studies for posoleucel in 2024 across three distinct indications – the prevention of clinically significant infection or disease from adenovirus (AdV), BK virus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV), the treatment of virus-associated hemorrhagic cystitis (vHC), and the treatment of AdV infection, all in allo-HCT patients. These viral infections have limited to no approved preventive therapies or treatment options, threatening patient survival.

131. The May 4, 2023 statements in paragraph 130 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing, while repeating positive Phase 2 study results, which were misleading because Defendants omitted to state the

material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

132. On May 4, 2023, the Company filed its Form 10-Q with the SEC that was signed by the Individual Defendants ("1Q23 10-Q"). The 1Q23 10-Q stated:

**Posoleucel is being studied in three ongoing Phase 3 registrational trials for three distinct indications** - the prevention of clinically significant infections from multiple viruses, the treatment of virus-associated hemorrhagic cystitis, or HC, and the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel. **The Company accelerated the multi-prevention study in recognition of the fact that prevention best addresses patients' unmet medical needs. Data readouts from all three trials are expected in 2024**

133. The May 4, 2023 statements in paragraph 132 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended

to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.

#### **E. May 9, 2023 Bank of America Global Healthcare Conference**

134. On May 9, 2023, Defendant Brainard participated in the Bank of America Global Healthcare Conference (“Bank of America Presentation”) on behalf of AlloVir.

135. During the Bank of America Presentation, Defendant Brainard responded to a question by BofA Securities, Research Division - Research Analyst Cameron T. Bozdog:

Q: And touching a little bit on the data you've seen so far in the Phase II, 88% of patients were free of clinically significant infections through 14 weeks. Can you put this into context for us?

A: **So we have now 3 positive Phase II data sets with posoleucel.** The first is in the treatment setting, refractory and resistant patients where we had over a 90% response rate across our 6 different target viruses. That study has been published. It came out of the Baylor College of Medicine. And then more recently, we had a Phase II prevention study, which enabled the initiation of our Phase III study that started last year. Those results were presented at ASH initially in 2021 and then again in 2022 and most recently at EBMT.

And like you said, really a dramatic response, whereby **88% of patients after dosing at the primary endpoint week 14 were free of clinically significant infections.** So hadn't developed one or more of these infections that are so common in the post-transplant space. And we were really happy to see that now we have the longer-term follow-up, and we reported at the European meeting in March that our day 400 non-relapse mortality rate was 0% in these patients.

Now it's a single-arm study, so we don't have a control arm, but if you look in the literature at what you might expect in a high-risk allograft transplant patient population, the reported rates of non-relapse mortality range between 9% and 16%. So we're really excited with this idea that not only can you prevent near-term morbidity of these infections, but you can also really help the patient on that trajectory towards recovery and preventing all of those non-relapse-related problems such as infection, but also graft-versus-host disease, organ dysfunction, which are all interrelated from becoming an issue and getting a patient into trouble.

136. The May 9, 2023 statements in paragraph 135 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, while repeating the positive results from the MVP Phase 2 Study, which was

misleading because Defendant Brainard omitted to state the material fact that Defendant Brainard knew the Company would not proceed with the FDA approval process because available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

#### **F. August 3, 2023 Corporate Presentation and Second Quarter 2023 Financial Results**

137. On August 3, 2023 AlloVir published a press release reporting its financial results for the second quarter of 2023.

138. The August 3, 2023 press release stated:

The Company's three Phase 3 global registrational trials for its allogeneic, off-the-shelf, virus-specific T cell therapy, posoleucel, in three distinct, first-to-market indications in allo-HCT patients continue to enroll, **with data anticipated in second half of 2024** ... "We are excited to be advancing our company's three Phase 3 global registrational trials of posoleucel for three indications that threaten allo-HCT recipients. Treating and preventing life-threatening viral infections using T cells that focus on restoring natural immunity addresses a significant unmet need for allo-HCT patients, which could have a significant impact on patient outcomes, morbidity, and survival," said Diana Brainard, M.D., Chief Executive Officer, AlloVir. "**We are very pleased with our progress to date and are on track to report data from all three studies in the second half of 2024.**"

139. The August 3, 2023 statements in paragraph 138 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, while repeating the positive results from the MVP Phase 2 Study, which was misleading because Defendants omitted to state the material fact that Defendants knew the

Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

140. The August 3, 2023 press release highlighted positive results from the MVP Phase 2 Study and noted that data from the Trials is anticipated in late 2024:

AlloVir delivered an oral presentation at the 49th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023) **detailing positive results from the Phase 2 study of posoleucel for the prevention of clinically significant infections from six common and devastating viruses in allo-HCT recipients**, including 0% non-relapse mortality at the 52-week follow-up visit. ... **Data from three Phase 3 registrational trials of posoleucel in three indications for allo-HCT patients is anticipated in the second half of 2024.**

141. The August 3, 2023 statements in paragraph 140 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, while repeating the positive results from the MVP Phase 2 Study, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB's analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that

continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

142. On August 3, 2023, the Company published its Form 10-Q with the SEC reporting financial results for the same quarter (the “2Q23 10-Q”). The 2Q23 10-Q was signed by the Individual Defendants and stated:

**Posoleucel is being studied in three ongoing Phase 3 registrational trials for three distinct indications** - the prevention of clinically significant infections from multiple viruses, the treatment of virus-associated hemorrhagic cystitis, or HC, and the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel. **We have accelerated the multi-prevention study in recognition of the fact that prevention best addresses patients’ unmet medical needs. Data readouts from all three trials are expected in 2024.**

143. The August 3, 2023 statements in paragraph 142 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for this application. The DSMB for the MVP Phase 3 Trial had performed the futility analysis mandated by AlloVir, and based on the DSMB’s analysis of the available data from the MVP Phase 3 Trial, the DSMB recommended to Defendants that continuing the MVP Phase 3 Trial was futile because it was failing to meet its primary efficacy endpoint. *See ¶¶ 47-63, 96, 99-100, 156-160, 161-180.*

**G. September 11, 2023 Morgan Stanley Global Healthcare Conference**

144. On September 11, 2023, Defendant Brainard participated in the Morgan Stanley Global Healthcare Conference with Morgan Stanley, Research Division - Equity Analyst, Michael Eric Ulz (the “Morgan Stanley Conference”).

145. During the Morgan Stanley Conference, Defendant Brainard touted the viability of the three Phase 3 Trials:

**So we have data from 3 Phase II trials and focusing on the Phase II prevention data** that was an open-label, single-arm study where we dosed 26 patients post allogeneic stem cell transplant with posoleucel and gave them 7 doses of posoleucel separated by 2 weeks. So dosing interval over a 12-week period. And what we looked for was signs or symptoms of clinically significant infection to any one of our target viruses over the -- through the primary endpoint at week 14 and we had expected to see anywhere between 50% to 70% of patients developing a clinically significant infection based on what the literature tells us about how commonly these infections occur. **What we saw was quite encouraging.** Only 3 of the 26 patients developed clinically significant infections; 2 patients developed CMV; 1 patient developed an adenoviral infection. And so this rate of about 12% was substantially lower than we would have predicted. And based on the strength of these data as well as the compelling safety data demonstrating, we saw no suggestion of cytokine release syndrome, which to date hasn’t been an issue with VSTs with the recurrent dosing.

146. The September 11, 2023 statements in paragraph 145 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, while repeating the positive results from the MVP Phase 2 Study, which was misleading because Defendant Brainard omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial and the VHC Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for these applications. The DSMBs for both the MVP Phase 3 Trial and VHC Phase 3 Trial had performed the futility analyses mandated by AlloVir, and based on the DSMBs’ analyses of the available data from the MVP Phase 3 Trial and VHC Phase 3 Trial, the DSMBs recommended to Defendants

that continuing the MVP Phase 3 Trial and VHC Phase 3 Trial was futile because they were failing to meet their primary efficacy endpoints. See ¶¶ 47-63, 64-80, 96, 99-100, 156-160, 161-180.

147. Defendant Brainard answered the following question during the Morgan Stanley Conference:

Q: I know you've had conversations with, but do you think that's highly likely that you'll be able to figure out what the path forward is here and have some agreement? Or is there any area where you're particularly I don't know, worried where the FDA might focus on or...

A: Well, I mean, I think that we have a good batting average in terms of having successfully done this with our other trials. It's always a challenge when you're in a new area, and I think that I have confidence we can get there. Sometimes it takes more than 1 conversation. That's fine. We can do that. We're committed to the -- to these patients. **And we also, I think, have a little bit more luxury because posoleucel is already in Phase III for these stem cell transplant indications. We don't want patients to have to wait. At the same time, we do think that demonstrating safety and efficacy with the drug in other clinical settings may help us in terms of allowing people to see a greater potential benefit for patients in other settings.**

148. The September 11, 2023 statements in paragraph 147 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial and the VHC Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable for these applications. The DSMBs for both the MVP Phase 3 Trial and VHC Phase 3 Trial had performed the futility analyses mandated by AlloVir, and based on the DSMBs' analyses of the available data from the MVP Phase 3 Trial and VHC Phase 3 Trial, the DSMBs recommended to Defendants that continuing the MVP Phase 3 Trial and VHC Phase 3 Trial

was futile because they were failing to meet their primary efficacy endpoints. *See ¶¶ 47-63, 64-80, 96, 99-100, 156-160, 161-180.*

#### **H. November 2, 2023 Press Release and Third Quarter 2023 Financial Results**

149. On November 2, 2023 AlloVir published a press release announcing its financial results from the third quarter of 2023.

150. The November 2, 2023 press release stated:

AlloVir continues to progress its highly innovative lead therapeutic candidate, posoleucel, by enrolling globally in three Phase 3 trials for first-to-market indications. **AlloVir is in a position of strength with significant financial resources to support operations through topline data readouts for all three trials anticipated in the second half of 2024.**

151. The November 2, 2023 statements in paragraph 150 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data from the Trials showed that proceeding with the Trials was futile and thus posoleucel would not obtain FDA approval and become commercially viable. The DSMBs for the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trials had performed the futility analyses mandated by AlloVir, and based on the DSMBs' analyses of the available data from the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trial, the DSMBs recommended to Defendants that continuing the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trial was futile because they were failing to meet their primary efficacy endpoints. *See ¶¶ 47-63, 64-80, 81-94, 96, 99-100, 156-160, 161-180.*

152. The Company's November 2, 2023 press release stated:

The company's Phase 3 registrational trials of posoleucel in allo-HCT patients continue to enroll with data anticipated from all three trials in the second half of 2024. ... AlloVir's lead product, posoleucel, is in late-stage clinical development as an allogeneic, off-the-shelf, multi-virus-specific T cell therapy targeting six viral pathogens in immunocompromised individuals: adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). In a Phase 2 open-label study of posoleucel for the prevention of clinically significant infections due to the six viruses posoleucel targets, 88% of allo-HCT patients who received posoleucel remained free of clinically significant infections through week 14, the primary endpoint. Moreover, the non-relapse mortality rate in patients who received posoleucel was 0% through the 52-week follow-up visit. Additionally, in the positive Phase 2 proof-of-concept CHARMS treatment study, which enrolled allo-HCT recipients infected by one or more of the six viruses posoleucel targets, more than 90% of patients who failed conventional treatment and received posoleucel demonstrated a complete or partial clinical response based on predefined criteria.

153. The November 2, 2023 statements in paragraph 152 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, while repeating the positive results from the MVP Phase 2 Study and the CHARMS Phase 2 Study, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial, the VHC Phase 3 Trial, and the ADV Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable. The DSMBs for the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trials had performed the futility analyses mandated by AlloVir, and based on the DSMBs' analyses of the available data from the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trial, the DSMBs recommended to Defendants that continuing the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trial was futile because they were failing to meet their primary efficacy endpoints. See ¶¶ 47-63, 64-80, 81-94, 96, 99-100, 156-160, 161-180.

154. On November 2, 2023, the Company published its Form 10-Q with the SEC reporting financial results for the same quarter (the “3Q23 10-Q”). The 3Q23 10-Q was signed by the Individual Defendants and stated:

**Posoleucel is being studied in three ongoing Phase 3 registrational trials for three distinct indications** - the prevention of clinically significant infections from multiple viruses, the treatment of virus-associated hemorrhagic cystitis, or HC, and the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel. **Data readouts from all three trials are expected in the second half of 2024.**

155. The November 2, 2023 statements in paragraph 154 above assured investors that posoleucel was on track to complete the Phase 3 Trials and become a commercially viable product for AlloVir, with representations that the three Phase 3 Trials were ongoing and data readouts were expected in 2024, which was misleading because Defendants omitted to state the material fact that Defendants knew the Company would not proceed with the FDA approval process because the available data showed that proceeding with the MVP Phase 3 Trial, the VHC Phase 3 Trial, and the ADV Phase 3 Trial was futile and thus posoleucel would not obtain FDA approval and become commercially viable. The DSMBs for the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trials had performed the futility analyses mandated by AlloVir, and based on the DSMBs’ analyses of the available data from the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trial, the DSMBs recommended to Defendants that continuing the MVP Phase 3 Trial, VHC Phase 3 Trial, and ADV Phase 3 Trial was futile because they were failing to meet their primary efficacy endpoints. See ¶¶ 47-63, 64-80, 81-94, 96, 99-100, 156-160, 161-180.

## VI. THE TRUTH IS REVEALED

156. On December 22, 2023, AlloVir issued a press release titled “AlloVir Provides Updates on Phase 3 Clinical Development Program for Posoleucel, an Allogeneic Virus-Specific T Cell Therapy.” The December 22, 2023 press release stated:

AlloVir [ . . . ] today provided an update on its three Phase 3 clinical trials with posoleucel, an investigational off-the-shelf multi-virus-specific T cell therapy, which targets six viral pathogens in immunocompromised individuals: adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). The company will discontinue its three global Phase 3 posoleucel studies – for prevention of clinically significant infections or diseases by multiple viruses, treatment of virus-associated hemorrhagic cystitis (vHC), and treatment of adenovirus (AdV) – following allogeneic hematopoietic cell transplant (allo-HCT). The company made the determination following three pre-planned analyses by three independent Data Safety Monitoring Boards (DSMBs) each of which recommended stopping its respective trial for futility after a review of the data suggested that each study was unlikely to meet its primary endpoint. There were no observed safety concerns raised by any of the DSMBs.

....

[Defendant] Brainard continued, “We established pre-planned futility analyses across these three Phase 3 trials, as each assessed a potentially highly innovative treatment for patients suffering with severe and complex medical conditions lacking significant prior clinical development, and we also expected the trials would require substantial additional capital to bring them to completion. With these current results, we will immediately shift our focus to preserve our substantial remaining capital, review our pipeline and assess strategic options.”

157. On this news, AlloVir’s stock price fell \$1.57 per share, or 67.38%, to close at \$0.76 per share on December 22, 2023.

158. Analysts were shocked by the revelation that the Company was abruptly terminating the Trials. A December 22, 2023 analyst report from Piper Sandler stated: “Unbeknownst to us, management had planned futility analyses of all three P3 studies of posoleucel (multi-virus prevention, treatment of vHC and treatment of adenovirus infections in allo-HSCT patients). While the timing is surprising, even more surprising to us is the outcome, given all the data produced with this therapy to date.” The December 22, 2023 Piper Sandler analyst report further stated that, “we are doubly surprised in that it was never disclosed that these trials had planned futility analyses baked into their design, let alone the timing.”

159. A December 22, 2023 J.P. Morgan analyst report had a negative reaction: “This is, of course, a disappointing and surprising outcome given what we had considered to be de-risking mid-stage data for the product.”

160. As a result of Defendants’ misleading statements and omissions, Plaintiffs and other Class members have suffered significant damages.

## **VII. ADDITIONAL ALLEGATIONS OF SCIENTER**

161. Defendants acted with scienter in that they knew and disregarded, that the public documents and statements they issued and disseminated to the investing public in the name of the Company or in their own name during the Class Period were materially false and misleading.

162. Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of misleading statements and documents as primary violations of the federal securities laws. The Individual Defendants, by virtue of their receipt of the recommendation of the DSMBs futility analyses, their control over, and/or receipt and/or modification of AlloVir’s allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

163. As highly educated doctors and experienced pharmaceutical executives, the Individual Defendants were intimately acquainted with the design of clinical trials and the related FDA regulations. In particular, as the architects of posoleucel’s three Phase 3 Trials, they were well aware posoleucel would not be able to obtain FDA approval if the result of the DSMBs’ futility analyses was to terminate the Trials prior to their completion.

164. The Individual Defendants knew and disregarded the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the

knowledge and complicity of the personnel at the highest levels of the Company, including the Individual Defendants.

165. Individual Defendants, because of their positions within AlloVir, made or controlled the contents of the Company's public statements during the Class Period. The Individual Defendants were provided with or had access to the information alleged herein to be false or misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, the Individual Defendants knew and disregarded that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were materially false and misleading. As a result, the Individual Defendants are responsible for the accuracy of AlloVir's corporate statements and are therefore responsible and liable for the representations contained therein.

166. The Statistical Analysis Plan and Study Protocol documents designed by AlloVir for each of the Trials set forth that each Trial would have a DSMB performing a futility analysis. These documents were signed by representatives for AlloVir and governed the Phase 3 Trials. Accordingly, Defendants had unique material knowledge regarding the DSMBs and the analyses it would engage in. Defendants concealed this facet of the Phase 3 Trials from the public during the entirety of the time that the Phase 3 Trials were active. The Statistical Analysis Plan and Study Protocol for each of the Trials only became publicly available months after the end of the Class Period.

167. The DSMBs for each of the Phase 3 Trials were mandated by AlloVir to routinely monitor the preliminary results of the Trials, make assessments on an ongoing basis, and make recommendations to AlloVir regarding the continuation of the Trials. *See* MVP SP at 61 ("the

DSMB will assess safety on an ongoing basis and will make recommendations on study continuation.”); VHC SAP at 26 (DSMB will “routinely monitor safety and evaluate prespecified interim analyses to stop the study early for futility.”); ADV SP at 16, 71(DSMB will “routinely monitor patient safety and evaluate prespecified interim analyses for futility”).

168. The DSMBs followed their mandate to make recommendations to AlloVir regarding the Trials. After the Class Period, it was disclosed that AlloVir received communications from the DSMBs throughout the Trials. For example, the ADV SP disclosed that on May 16, 2023, the DSMB made a recommendation to AlloVir to expand the eligible patient population. *See* ADV SP at 35. Additionally, the MVP SP disclosed that the MVP DSMB made a recommendation to AlloVir to proceed with the Phase 3 study of MVP prior to the Class Period. *See* MVP SP at 31.

169. AlloVir never announced any topline or preliminary results from any of the Phase 3 Trials during the multi-year period in which they were active, leading investors and analysts to reasonably believe that each of the three Trials had successfully passed through any futility analysis checkpoint.

170. All three Phase 3 Trials began at different times, nearly two years apart. The three Phase 3 Trials also used different time frames for when the drug’s efficacy would be evaluated after it was administered. Likewise, the three Phase 3 Trials all required different numbers of patients enrolled before an interim analysis for futility would be performed the DSMB. Despite the vastly staggered start and end dates, different time frames for evaluation, and different numbers of enrollees required to trigger a futility analysis, AlloVir terminated all three Phase 3 Trials on the same exact date, finally revealing the previously known futility of continuing each of the trials (strategically announcing the news on the Friday before the Christmas holiday).

171. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, and disregarded the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

172. Defendants were motivated to conceal the results of the DSMBs' futility analyses because posoleucel represented a \$1 billion opportunity for the Company. On December 14, 2022, during a conference call with investors and analysts, Defendant Brainard represented that "Multi-virus prevention could be the most transformative for patients." Defendant Brainard explained that this was the largest commercial opportunity for the Company: "With approximately 41,000 allo-HCT patients per year globally that could potentially benefit from posoleucel, if approved, this also represents a blockbuster market opportunity of over the \$1 billion in peak sales annually."

173. Defendants were motivated to keep AlloVir's stock price artificially inflated to ensure there was sufficient demand for shares offered for sale in the Company's secondary offering, which raised \$70 million for the Company. On June 21, 2023, AlloVir announced a proposed public offering for \$75 million of common stock. The same day, AlloVir issued a second press release announcing additional details regarding the public offering. The second announcement provided that there were 20 million shares being offered at a price of \$3.75 per share, amounting to an estimated total of \$75 million in gross proceeds for the Company. On June 26, 2023, AlloVir announced that the stock offering had closed and the Company had raised a total of \$70.2 million through the offering.

174. Defendants' misleading statements regarding posoleucel concern critical aspects of the Company's core operations. The FDA approval of posoleucel was vital to AlloVir's financial success and the Company's existence.

175. Since AlloVir became a publicly traded company, posoleucel was the Company's most clinically advanced asset. During the Class Period, posoleucel represented AlloVir's best chance at obtaining FDA approval, and in turn it was the Company's clinical asset most likely to become a commercially viable product. Posoleucel represented an opportunity of potentially \$1 billion in annual sales, for a Company that has never had revenue.

176. Posoleucel was of paramount importance to AlloVir that Defendant Brainard, on behalf of AlloVir, regularly spoke at conferences with analysts and investors about posoleucel.

177. Analysts who covered AlloVir regularly reported on the posoleucel Phase 2 results, the posoleucel Trials, and the significance of the product to the Company.

178. When AlloVir terminated the posoleucel Trials, AlloVir's stock price collapsed and hundreds of millions of dollars in the Company's market capitalization were wiped out instantly.

179. Two weeks after AlloVir announced that it had terminated the posoleucel Trials, the Company reported that it was laying off 95% of its employees.

180. Posoleucel was of such importance to the Company that the Individual Defendants were required to, and did, have knowledge during the Class Period of the status of posoleucel's Trials, developments, and milestones, including the DSMBs' futility analyses.

### **VIII. LOSS CAUSATION**

181. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of AlloVir's publicly traded securities, by publicly issuing misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not misleading. The statements and omissions were materially false and/or

misleading because they failed to disclose material adverse information and/or misrepresented the truth about AlloVir's business, operations, and prospects as alleged herein.

182. During the Class Period, as detailed herein, AlloVir's securities were artificially inflated due to Defendants' misleading statements and omissions. When Defendants' misrepresentations and omissions were disclosed and became apparent to the market, the price of AlloVir securities fell as the prior artificial inflation came out.

183. As a result of purchases of AlloVir securities during the Class Period, Plaintiffs and the other Class members suffered economic loss, *i.e.*, damages, under the securities laws.

184. The decline in the price of AlloVir securities after the corrective disclosure on December 22, 2023 was a direct result of Defendants' misrepresentations being revealed to investors and the market.

185. The decline in the price of AlloVir securities was also the result of the materialization of the concealed investment risks concerning AlloVir.

186. On December 22, 2023, Defendants announced that all three of the Phase 3 Trials were to be terminated, effective immediately. AlloVir's stock price dropped soon after the corrective disclosure. On this news, AlloVir stock fell \$1.57 per share, or 67.38%, to close at \$0.76 per share on December 22, 2023.

187. The timing and magnitude of the price decline in AlloVir securities negates any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' statements. The economic loss, *i.e.*, damages, suffered by Plaintiffs and the other Class members was a direct result of Defendants' misstatements and omissions and the subsequent

significant decline in the value of AlloVir securities when Defendants' misrepresentations were revealed.

188. Multiple analysts reported on the surprising news. A December 22, 2023 analyst report from Piper Sandler stated: "Unbeknownst to us, management had planned futility analyses of all three P3 studies of posoeucel (multi-virus prevention, treatment of vHC and treatment of adenovirus infections in allo-HSCT patients). While the timing is surprising, even more surprising to us is the outcome, given all the data produced with this therapy to date." Additionally, a December 22, 2023 J.P. Morgan analyst stated: "This is, of course, a disappointing and surprising outcome given what we had considered to be de-risking mid-stage data for the product."

## **IX. CLASS ACTION ALLEGATIONS**

189. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the Company's securities during the Class Period; and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

190. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, AlloVir securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by AlloVir or its transfer agent and may be notified of the

pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

191. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

192. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

193. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are: whether the federal securities laws were violated by Defendants' acts as alleged herein; whether the Individual Defendants caused AlloVir to issue misleading statements during the Class Period; whether Defendants acted knowingly in issuing misleading statements; whether the prices of AlloVir securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

194. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## X. APPLICABILITY OF PRESUMPTION OF RELIANCE

195. The market for AlloVir's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, AlloVir's securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased the Company's securities relying upon the integrity of the market price of AlloVir's securities and market information relating to AlloVir and have been damaged thereby.

196. During the Class Period, the artificial inflation of AlloVir's securities was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about the Trials. These material misstatements and/or omissions created an unrealistically positive assessment of AlloVir and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when the truth was disclosed, negatively affected the value of the Company shares. Defendants' materially misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

197. At all relevant times, the market for AlloVir's securities was an efficient market for the following reasons, among others: (a) AlloVir shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market; (b) As a regulated issuer, AlloVir filed periodic public reports with the SEC and/or the NASDAQ; (c) AlloVir regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of

major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or (d) AlloVir was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

198. As a result of the foregoing, the market for AlloVir's securities promptly digested current information regarding AlloVir from all publicly available sources and reflected such information in the price of AlloVir securities. Under these circumstances, all purchasers of AlloVir securities during the Class Period suffered similar injury through their purchase of AlloVir securities at artificially inflated prices and a presumption of reliance applies.

199. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

**FIRST CAUSE OF ACTION**

**VIOLATIONS OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10B-5  
PROMULGATED THEREUNDER**

**(AGAINST THE COMPANY AND INDIVIDUAL DEFENDANTS)**

200. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein and further allege as follows:

201. This Count is asserted pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by the SEC, on behalf of Plaintiffs and members of the Class against the Company and the Individual Defendants.

202. During the Class Period, the Company and the Individual Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did:

(a) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (b) cause Plaintiffs and other members of the Class to purchase AlloVir's publicly traded securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each Individual Defendant, took the actions set forth herein. The Company and the Individual Defendants (a) employed devices, schemes, and artifices to defraud; (b) made materially misleading statements and omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's publicly traded securities in an effort to maintain artificially high market prices for AlloVir's publicly traded securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

203. The Company and Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about AlloVir's financial well-being, operations, and prospects, as specified herein.

204. During the Class Period, the Company and the Individual Defendants made the materially misleading statements specified above, which they knew to be misleading when made in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

205. The Company and the Individual Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, and disregarded the true facts that were available to them. The Company and the Individual Defendants engaged in this misconduct to conceal AlloVir's true condition from the investing public and to support the artificially inflated prices of the Company's publicly traded securities.

206. As a result of the dissemination of the materially misleading information and/or failure to disclose material facts, as set forth above, the market price of AlloVir's publicly traded securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, and/or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class purchased AlloVir's securities during the Class Period at artificially high prices and were damaged thereby.

207. Plaintiffs and the Class would not have purchased the Company's publicly traded securities at the prices they paid, or at all, had they been aware that the market prices for AlloVir's publicly traded securities had been artificially inflated by the Company and the Individual Defendants' fraudulent course of conduct.

208. As a direct and proximate result of the Company's and the Individual Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's publicly traded securities during the Class Period.

209. By virtue of the foregoing, the Company and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

### **SECOND CAUSE OF ACTION**

#### **VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT (AGAINST THE INDIVIDUAL DEFENDANTS)**

210. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein and further allege as follows:

211. This Count is asserted pursuant to Section 20(a) of the Exchange Act against the Individual Defendants on behalf Plaintiffs and members of the Class.

212. As alleged above, AlloVir is liable to Plaintiffs and members of the Class based on the materially misleading statements and omissions as set forth above, pursuant to Section 10(a) of the Exchange Act.

213. Throughout the Class Period, the Individual Defendants were controlling persons of AlloVir within the meaning of Section 20(a) of the Exchange Act as alleged herein, and culpable participants in the fraud alleged herein.

214. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the Company's products, operations, and Trials, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are materially misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's financial statements, reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

215. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence, the decision-making of AlloVir, including the content of its financial statements, filings with the SEC, press releases, and other public statements.

216. Given their individual and collective responsibilities for managing AlloVir throughout the Class Period, the Individual Defendants were regularly presented to the market as the individuals responsible for the Company's day-to-day business and operations, as well as its strategic direction.

217. As set forth above, the Individual Defendants acted knowingly and intentionally, in such a manner as to constitute willful fraud and deceit upon Plaintiffs and other members of the Class who purchased AlloVir's publicly traded securities stock during the Class Period.

218. Each of the Individual Defendants culpably participated in a meaningful sense in the fraud alleged herein. By reason of the foregoing, and by virtue of their position as controlling

persons, the Individual Defendants are liable to Plaintiffs and members of the Class for violations of Section 20(a) of the Exchange Act.

## **XI. PRAYER FOR RELIEF**

219. Wherefore, Plaintiffs pray for relief and judgment as follows:

- a. Determining that this action is a proper class action and certifying Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure;
- b. Awarding damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' violations of the Securities Exchange Act of 1934, in an amount to be proven at trial, including pre- and post-judgment interest thereon;
- c. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action including counsel fees and expert fees; and
- d. Awarding such other and further relief as the Court may deem just and proper.

## **XII. JURY TRIAL DEMANDED**

220. Plaintiffs hereby demand a trial by jury.

DATED: June 17, 2024

Respectfully submitted,

**HUTCHINGS BARSAMIAN  
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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing document was filed with the Court's electronic case filing (ECF) system on June 17, 2024, which caused an electronic copy of this document to be served on all counsel of record in this matter who have registered for ECF service.

/s/ *Theodore M. Hess-Mahan*  
Theodore M. Hess-Mahan